

CLAIMS

- 1 ✓ 1. A nucleic acid vector containing a non-coding, immunostimulatory polynucleotide,
2 wherein the immunostimulatory polynucleotide is comprised of six nucleotides
3 arranged in the sequence 5'-purine-purine-unmethylated CpG-pyrimidine-
4 pyrimidine-3'; and wherein further the immunostimulatory polynucleotide
5 stimulates development of a Th1 immune phenotype and cell-mediated immunity
6 in response to co-delivery of antigen to a mammalian host.
- 1 2. The nucleic acid vector of Claim 1 wherein the vector is a plasmid or cosmid.
- 1 3. The nucleic acid vector of Claim 2 wherein the plasmid or cosmid is naked.
- 1 4. The nucleic acid vector of Claim 1 further comprising a polynucleotide which
2 encodes a polypeptide.
- 1 5. The nucleic acid vector of Claim 4 wherein the polypeptide is an antigen or
2 immunostimulatory antigen fragment.
- 1 6. The nucleic acid vector of Claim 5 wherein the polypeptide is a cytokine.
- 1 7. The nucleic acid vector of Claim 4 wherein the polypeptide is a T lymphocyte
2 epitope.
- 1 8. The nucleic acid vector of Claim 4 wherein expression of the encoded
2 polynucleotide is under the control of a nuclear receptor promoter.

09265191.031099

9 The nucleic acid vector of Claim 1 wherein the immunostimulatory
polynucleotide is selected from the group of polynucleotides consisting of:
AACGTT (SEQ.ID.No.1); GACGTC (SEQ.ID.No.4); AGCGCT (SEQ.ID.No.5);
CGACGATCGTCG (SEQ.ID.No.15); CAACGTTG (SEQ.ID.No.17);
ACAACGTTGT (SEQ.ID.No.18); AACAACGTTGTT (SEQ.ID.No.19), or
CAACAACGTTGTTG (SEQ.ID.No.20).

10. A nucleic acid vector consisting essentially of pKCB-1aaZ.

11. A nucleic acid vector consisting essentially of pKCB-2aaZ.

12. A method for stimulating the development of a Th1 immune phenotype and cell-mediated immunity in response to an antigen comprising co-delivering the antigen and a nucleic acid vector into a tissue of a mammalian host;

wherein the nucleic acid vector contains a non-coding, immunostimulatory polynucleotide comprised of six nucleotides arranged in the sequence 5'-purine-purine-unmethylated CpG-pyrimidine-pyrimidine-3'; and

wherein further the immunostimulatory polynucleotide stimulates the development of the Th1 phenotype and cell-mediated immunity in response to the co-delivered antigen.

09265191-031099

13. The method according to Claim 12 wherein the nucleic acid vector is a plasmid or cosmid.
14. The method according to Claim 13 wherein the nucleic acid vector is naked.
15. The method according to Claim 12 wherein the host tissue into which the nucleic acid vector is co-delivered with antigen is skin.
16. The method according to Claim 12 wherein the nucleic acid vector encodes at least one polypeptide.
17. The method according to Claim 16 wherein at least one of the encoded polypeptides is the antigen or an immunostimulatory fragment of the antigen.
18. The method according to Claim 16 wherein at least one of the encoded polypeptides is a cytokine.
19. The method according to Claim 16 wherein at least one of the encoded polypeptides is a T lymphocyte epitope.
20. The method according to Claim 17 wherein the antigen is expressed in antigen presenting cells in the host skin.
21. A method according to Claim 17 wherein the nucleic acid vector is coated onto the tynes of a multiple tyne device and is administered by penetrating the skin of the host with the tynes.

09265191.031099

- 1 22. A method according to Claim 12 wherein the nucleic acid vector is introduced
2 by absorption through skin treated with a keratinolytic agent.
- 1 23. A method according to Claim 16 wherein expression of the encoded polypeptide
2 by the nucleic acid vector is under the control of a nuclear receptor promoter.
- 1 24. A DNA or RNA virus into which at least one non-coding, immunostimulatory
2 polynucleotide has been inserted, wherein the immunostimulatory polynucleotide
3 is comprised of six nucleotides arranged in the sequence 5'-purine-purine-
4 unmethylated CpG-pyrimidine-pyrimidine-3'; and wherein further the
5 immunostimulatory polynucleotide stimulates the development of a Th1 immune
6 phenotype and cell-mediated immunity in response to co-delivery of an antigen
7 to a mammal.
- 1 25. The method according to Claim 12 wherein the host tissue into which the nucleic
2 acid vector is co-delivered with antigen is mucosa.

09265191.031099

Sub
A2

add
B1

add C2